REMARKS

Status of Claims

Claims 23-37 are currently pending and under consideration.

Claim Amendments

Claims 23 and 37 have been amended to recite a "calcium or quaternary ammonium" salt thereof. Support for this amendment can be found in the specification on page 2, line 34 – page 3, line 1.

Claim 38 has been added to recite that the coating is an enteric coating. Support for this claim can be found on page 23, lines 20-21.

Rejection of Claims under 35 U.S.C. Section 102(b)

The Office has rejected claim 23 under 35 U.S.C. Section 102(b) for being anticipated by Boyer (U.S. Patent No. 4,800,079). Specifically, the Office says that Boyer teaches a pharmaceutical composition of "fenofibrate and its derivatives" and a binder. According to the Office, the phrase "fenofibrate and its derivatives" as used by Boyer refers to a compound having a specific formula I. The Office states that formula I encompasses fenofibric acid. Moreover, with respect to a binder, the Office states that Boyer teaches binders such as methacrylic polymers, polyvinylpyrolidone, cellulose derivatives and polyethylene glycols (pointing to claim 2). Applicants respectfully traverse the rejection.

The phrase "fenofibrate and its derivatives" referred to by the Examiner appears only in two places in Boyer, specifically, in the Background of the Invention, namely, in column 1, line 11 and lines 47-48. This phrase is not used by Boyer at all in connection with the description of his invention. As the Examiner noted, Formula I as recited by Boyer encompasses fenofibric acid. However, despite the fact that fenofibric acid is encompassed within Formula I, Applicants submit that a reading of Boyer **in its entire**ty would make it abundantly clear to one skilled in the art that Boyer's invention relates to **fenofibrate** and to formulations which improve the absorption of fenofibrate in the digestive system and not to fenofibric acid. Specifically, in column 2, lines 3-8, Boyer states, "[I]t has been observed that fenofibrate has poor solubility in aqueous liquids, thereby giving rise to non-uniform absorption in the digestive tube, and in accordance with the **present invention a galenical preparation has been devised which considerably improves absorption by the digestive tube** (emphasis added)."

The composition (i.e., galenical preparation) taught by Boyer comprises a granule. Each granule contains an inert core, a layer of crystalline microparticles of fenofibrate and a protective layer. Boyer states in column 3, lines 15-23, that "[T]he fenofibrate layer structure is similar to that of a sponge, with the pores containing microparticles of fenofibrate. The sponge is constituted by a binder which is soluble in an aqueous medium: methacrylate or polyvinylpyrolidone. Once the binder has dissolved, the microparticles of fenofibrate are released and can prevent[1] [sic] their entire areas to the process of absorption in the intestinal aqueous medium."

As pointed out in Applicants' Amendment filed on October 7, 2008, due to its poor solubility, fenofibrate is difficult to formulate. Since 1976, at least three different approaches were developed by those skilled in the art to improve the bioavailability of fenofibrate. These approaches are: (1) reducing the size of fenofibrate (to increase the surface area thus resulting in better dissolution); (2) creating solid dispersions of fenofibrate (the amorphous form should exhibit faster dissolution); and (3) using lipid systems (used to solubilize fenofibrate). As mentioned in footnote 1 in that Amendment, in contrast to fenofibrate, fenofibric acid (the active metabolite of fenofibrate) is **highly soluble**.

As mentioned above, read in its entirety, Boyer teaches a composition comprising granules. Each granule contains a layer of fenofibrate and a protective layer. The fenofibrate layer contains crystalline microparticles having a dimension not greater than 30 microns, and preferably less than 10 microns. The purpose of the fenofibrate layer is to improve the solubility of the fenofibrate after ingestion. This is consistent with the approaches used since 1976 to improve the bioavailability of fenofibrate. Given the highly soluble nature of fenofibric acid and its calcium and quaternary ammonium salts, a mechanism for improving its bioavailability, such as that described by Boyer, is not necessary. Therefore, it is not surprising that Boyer does not used the phrase "fenofibrate and its derivatives" anywhere in describing his invention. Thus, because Boyer simply does not teach a composition containing fenofibric acid or calcium or quaternary ammonium salts thereof, Applicants submit that the claimed invention is not anticipated and that this rejection is now moot and should be withdrawn.

Rejection of Claims Under 35 U.S.C. Section 103(a)

Claims 23-37 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Boyer in view of Kothrade et al. (U.S. Patent No. 6,284,803). As discussed above in connection with the 35 U.S.C. Section 102(b) rejection, the Office says that Boyer teaches a pharmaceutical composition of fenofibrate and its derivatives and a binder. The Office points to formula I described by Boyer and argues that this formula encompasses fenofibric acid. Despite this, the Office states that Boyer is deficient in that the limitations of

[1] Applicants submit that this should read "present" instead of "prevent".

the dependent claims are "not explicitly stated in the composition." The Office cites Kothrade et al. as reciting the limitations of the dependent claims. Specifically, the Office says that it would be *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine the components of Kothrade et al. for the formulation of Boyer to arrive at a fenofibric acid composition for pharmaceutical oral administration. According to the Office, the "expected" result would be an effective lipid-regulating tablet in dosage form. Applicants respectfully traverse.

As discussed above, Boyer teaches a fenofibrate formulation and does not disclose or suggest a composition comprising fenofibric acid or calcium or quaternary ammonium salts. As Applicants discussed in their Amendment filed on October 7, 2008, Kothrade et al. is directed to solid dosage forms that comprise a polymeric binder and an active ingredient, wherein the polymeric binder consists of copolymerized units of (1) 15-83% w/w of at lest one N-vinyllactam; (2) 15-83% w/w of methyl methacrylate; (3) 2-70% of at least one other monomer; and (4) 9-9.9% w/w/ of at least one α,β-ethylenically unsaturated acid. Kothrade et al. teach in detail how to make the polymeric binder. Kothrade et al. do not disclose or suggest fenofibric acid. Thus, neither Boyer nor Kothrade et al., either individually or collectively, disclose or suggest formulating fenofibric acid into a composition. In view thereof, Applicants submit that the claimed invention is not obvious and that this rejection is now moot and should be withdrawn.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Office have any questions or would like to discuss any matters in connection with the present application, the Office is invited to contact the undersigned at

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